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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,377	02/12/2001	Andre Rosenthal	147-211P	7286

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/647,377		ROSENTHAL ET AL.	
	Examiner		Art Unit	
	Scott Priebe		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 12, 13, 20, 21, 23-26, drawn to a nucleic acid molecule comprising nucleic acid encoding SEQ ID NO: 9, nucleic acid of SEQ ID NO: 8, or nucleic acid encoding a protein which hybridizes thereto, and the first recited method of using same, which is to produce a protein.

Group II, claim(s) 1-8, 12, 13, 20, 21, 23-26, drawn to a nucleic acid encoding SEQ ID NO: 14, nucleic acid of SEQ ID NO: 13, or nucleic acid encoding a protein which hybridizes thereto, and the first recited method of using same, which is to produce a protein. .

Group III, claim(s) 9, 12, 13, 22, drawn to the protein of SEQ ID NO: 9.

Group IV, claim(s) 9, 12, 13, 22, drawn to the protein of SEQ ID NO: 14.

Group V, claim(s) 10, drawn to an antibody which binds to the protein of SEQ ID NO: 9.

Group VI, claim(s) 10, drawn to an antibody which binds to the protein of SEQ ID NO: 14.

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Group VII, claim(s) 11, drawn to a nucleic acid of at least 15 nucleotides which hybridizes to a nucleic acid molecule of Group I.

Group VIII, claim(s) 11, drawn to a nucleic acid of at least 15 nucleotides which hybridizes to a nucleic acid molecule of Group II.

Group IX, claim(s) 14, 27, 28, drawn to a method of making a transgenic, non-human animal produced from an embryonic cell or egg cell transformed with a nucleic acid molecule of Group I, a second method of using the nucleic acid molecules of Group I.

Group X, claim(s) 14, 27, 28, drawn to a method of making a transgenic, non-human animal produced from an embryonic cell or egg cell transformed with a nucleic acid molecule of Group II, a second method of using the nucleic acid molecules of Group II.

Group XI, claim(s) 15, 18, 19, drawn to a transgenic, non-human animal transformed with a nucleic acid molecule of Group I, products made by a third method of using the nucleic acid molecules of Group I.

Group XII, claim(s) 15, 18, 19, drawn to a transgenic, non-human animal transformed with a nucleic acid molecule of Group II, products made by a third method of using the nucleic acid molecules of Group II.

Group XIII, claim(s) 16-19, drawn to a transgenic, non-human animal whose cells express lower levels of the protein of SEQ ID NO: 9 than in a corresponding wild type animal.

Group XIV, claim(s) 16-19, drawn to a transgenic, non-human animal whose cells express lower levels of the protein of SEQ ID NO: 9 than in a corresponding wild type animal.

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The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I, III, V, VII, IX, XI, and XIII relate to a different protein, the nucleic acid encoding it, antibodies that bind it, etc. from that of Groups II, IV, VI, VIII, X, XII, and XIV. The nucleic acid of the former, SEQ ID NO: 8, is purported to be a complete cDNA from mouse, whereas the nucleic acid of the latter, SEQ ID NO: 14 is a partial genomic sequence from human. The mouse protein, SEQ ID NO: 9, is substantially larger than that of human, SEQ ID NO: 14. The corresponding nucleic acid molecules and proteins of mouse and human are related by sequence homology, but are not identical, nor is it clear from the specification that these related sequences share the same function. Consequently, the mouse and human products do not share the same special technical features. For example, while the mouse nucleic acid might be used to make a transgenic mouse, it is not clear that the human sequence could be used to make a transgenic mouse.

Groups I, II, VII, VIII, IX-XII are directed to nucleic acids or transgenic animals made using the nucleic acid, Groups III and IV are directed to LOBO proteins, Groups V and VI are directed to antibodies to LOBO proteins, while Groups XIII and XIV are directed to transgenic animals that have reduced levels of LOBO proteins. Nucleic acids are structurally and functionally very different compounds than proteins. LOBO proteins and antibodies are structurally and functionally different proteins. Consequently, inventions directed to these

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different products do not share a special technical feature with each other. The transgenic animals of Groups XIII and XIV, as claimed, do not involve the isolated nucleic acid, isolated LOBO protein, or antibodies.

The nucleic acids of Groups VII and VIII are oligonucleotides which have the function of hybridizing to the isolated nucleic acids of Groups I and II, respectively, which have the function of encoding a protein. The vast majority of nucleic acids of Groups VII and VIII will not encode proteins, nor are they required to be fragments of nucleic acids which would encode the proteins. Nucleotide sequence variations which would make a nucleic acid unsuitable for expression of a protein, e.g. frame shifts and missense mutations, would not render them unsuitable for hybridization, unless such variation was extensive. Furthermore, the isolated nucleic acid molecules of Groups I and II are permitted to comprise sequences in addition to those which encode the recited protein, e.g. a vector backbone, and therefore, Groups VII and VIII include molecules which hybridize to these additional sequences. As a result, Groups VII and VIII embrace virtually any nucleic acid molecule of the prior art, e.g. a vector backbone. Consequently, the nucleic acids of Groups I and II do not share a special technical feature with the nucleic acids of Groups VII and VIII. With regard to the application of PCT Rule 13, 37 CFR 1.475 does not provide for multiple distinct products or multiple distinct methods of using a product as sharing unity of invention.

The transgenic animals made by the method of Groups IX and X comprise nucleic acids of Groups I or II in every cell, i.e. the nucleic acids are a permanent part of their genome. The

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transgenic animals of Groups XI and XII are transgenic animals which have been transformed with nucleic acid of Groups I or II, i.e. they carry some unspecified transgene as part of their genome and some of their cells are subsequently transformed with nucleic acid of Groups I or II. These two different types of transgenic animals are different products structurally, and presumably functionally. With regard to the application of PCT Rule 13, 37 CFR 1.475 does not provide for multiple distinct products or multiple distinct methods of using a product as sharing unity of invention. The transgenic animals of Groups XIII and XIV do not involve the isolated nucleic acid molecules of Groups I or II. As disclosed in the specification, the transgenic mouse having long bones was made using a nucleic acid construct unrelated to the nucleic acid molecules of Groups I and II.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

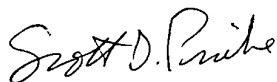
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry concerning administrative, procedural or formal matters relating to this application should be directed to Patent Analyst Patsy Zimmerman whose telephone number is (703) 308-8338. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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Primary Examiner
Technology Center 1600
Art Unit 1632